MEETING SUMMARY

New York State Medicaid Evidence Based Benefit Review Advisory Committee

Thursday, December 15, 2016
10:00 am – 3:30 pm
Empire State Plaza, Concourse
Meeting Room #1
Albany, NY

This meeting summary is being issued pursuant to Social Services Law section 365-d (6).

Background:

The Evidence Based Benefit Review Advisory Committee (the Committee) met on December 15, 2016. Ten committee members attended along with staff from the Center for Evidence Based Policy (CEbP) at Oregon Health and Science University (OHSU) and staff from the New York State (NYS) Department of Health (the Department).

Clinical evidence was presented on the topics identified below by OHSU's research physicians to the Committee. The Committee was tasked with making a recommendation regarding coverage for purposes of the Medicaid program. The specific topics and recommendations are discussed below.

- Implantable Infusion Pumps for non-cancer pain
- Lorcaserin (Belviq®)
- Digital Breast Tomosynthesis

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Topic Under Review: Implantable Infusion Pumps for non-cancer pain

Position of Public Presenters: Three members of the public that included a physician and two industry representatives made presentations in support of NYS Medicaid coverage of implantable infusion pumps for non-cancer pain.

Safety & Health Outcomes Data Submitted by the Public: There was no Safety or Health Outcomes Data submitted by the public.

Response of the Committee to Public Presentations: The Committee questioned public presenters on:

- the ability of patients to taper dose versus life-long use,
- the role of implantable infusion pumps as an alternative to chronic oral pain medication, and

- the accessibility of other forms of pain management therapy.

Clinical Evidence Presented to the Committee: See the following links to the evidence presented by CEbP at OHSU:
https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/implant_infusion_pump.pdf

https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/implant_infusion_pump_addition_sub.pdf

Summary of the Committee's deliberations: The Committee focused deliberations on:

- how implantable infusion pumps for non-cancer pain fit into the larger opioid misuse problem in NYS,
- whether opioids are the best treatment for chronic pain,
- why most studies measure pain scores when patient function is a better measure of effectiveness, and
- the need for additional studies on the effects of implantable infusion pumps on patient function.

Evidence-Based Systematic Assessment: See the "**Summary**" section on page 36 of CEbP at OHSU's Evidence-based systematic assessment of Implantable Infusion Pumps for Non-cancer Pain at the following link:
https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/implant_infusion_pump.pdf

Also, see the **"Summary"** section on page 11 of CEbP at OHSU's Evidence-based systematic assessment of the Additional Evidence Submissions on Implantable Infusion Pumps for Non-cancer Pain at the following link:
https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/implant_infusion_pump_addition_sub.pdf

The Committee's Findings and Recommendations: The Committee reviewed the OHSU Report and the systemic assessment of the evidence reviewed and presented by the CEbP at OHSU. The Committee unanimously recommended non-coverage of implantable infusion pumps for non-cancer pain.

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Topic Under Review: Lorcaserin (Belviq®)

Position of Public Presenters: Four members of the public that included one physician, one director of a weight control center and two industry representatives made presentations in support of NYS Medicaid coverage of lorcaserin (Belviq®) for weight management.

Safety & Health Outcomes Data Submitted by the Public:

1. Weissman NJ, Smith SR, Fain R, Hall N, Shanahan WR. Effects of lorcaserin on pre-existing valvulopathy: A pooled analysis of phase 3 trials. *Obesity (Silver Spring).* 2017 Jan;25(1): 39-44.
2. Shanahan WR, Rose JE, Glicklich A, Stubbe S, Sanchez-Kam M. Lorcaserin for Smoking Cessation and Associated Weight Gain: A Randomized 12-Week Clinical Trial. *Nicotine & Tobacco Research*, 2017 Aug 19(8): 944–951.
3. Hurt RT, Croghan IT, Schroeder DR, Hays JT, Choi D, Ebbert JO. Combination Varenicline and Lorcaserin for Tobacco Dependence Treatment and Weight Gain Prevention in Overweight and Obese Smokers: A Pilot Study. *Nicotine & Tobacco Research*, 2017 Aug 19(8): 994–998.
4. Handelsman Y, Fain R, Wang Z, Li X, Fujioka K, Shanahan W. Lorcaserin treatment allows for decreased number needed to treat for weight and glycemic parameters in week 12 responders with ≥5% weight loss. *Postgraduate Medicine*, 2016;128(8): 740-746.

Response of the Committee to Public Presentations: The Committee questioned public presenters on:

- the meaningfulness of the data presented by public presenters,
- the availability of studies comparing lorcaserin to bariatric surgery, and
- the impact of the drug's long-term use.

Clinical Evidence Presented to the Committee: See the following link to the evidence presented by CEbP at OHSU:
https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/belviq_dossier_review_belviq_final.pdf

Summary of the Committee's deliberations: The Committee focused deliberations on:

- the need for additional research regarding interactions between lorcaserin and other medications,
- the relative cost of lorcaserin compared to other weight loss drugs and treatments,
- the effectiveness of lorcaserin compared to other weight loss drugs and treatments, and
- the use of lorcaserin for some population(s) to avoid bariatric surgery.

Evidence-Based Systematic Assessment: See the "**Summary**" section on page 26 of CEbP at OHSU's evidence-based systematic assessment of Lorcaserin (Belviq®) at the following link:
https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/belviq_dossier_review_belviq_final.pdf

The Committee's Findings and Recommendations: The Committee reviewed the OHSU Report and the systemic assessment of the evidence reviewed and presented by the CEbP at OHSU. The Committee unanimously recommended non-coverage of lorcaserin (Belviq®) for the pharmacologic management of weight.

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Topic Under Review: Digital Breast Tomosynthesis (DBT)

Position of Public Presenters: Two members of the public that included one physician and one industry representative made presentations in support of NYS Medicaid coverage of digital breast tomosynthesis.

Safety & Health Outcomes Data Submitted by the Public:

1. Feig, S.A., Current status of screening mammography. *Obstet Gynecol Clin North Am*, 2002; 29(1): p. 123-36.
2. Pisano, E.D., et al., Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening. *New England Journal of Medicine*, 2005; 353(17): p. 1773-1783.
3. Skaane, P., et al., Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program. *Radiology*, 2013; 267(1): p. 47-56.
4. Ciatto, S., et al., Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. *Lancet Oncol*, 2013; 14(7): p. 583-9.
5. Haas, B.M., et al., Comparison of tomosynthesis plus digital mammography and digital mammography alone for breast cancer screening. *Radiology*, 2013; 269(3): p. 694-700.
6. Rose, S.L., et al., Implementation of breast tomosynthesis in a routine screening practice: an observational study. *AJR Am J Roentgenol*, 2013; 200(6): p. 1401-8.
7. Friedewald, S.M., et al., Breast cancer screening using tomosynthesis in combination with digital mammography. *JAMA*, 2014; 311(24): p. 2499-507.
8. Greenberg, J.S., et al., Clinical performance metrics of 3D digital breast tomosynthesis compared with 2D digital mammography for breast cancer screening in community practice. *AJR Am J Roentgenol*, 2014; 203(3): p. 687-93.
9. Lourenco, A.P., et al., Changes in Recall Type and Patient Treatment Following Implementation of Screening Digital Breast Tomosynthesis. *Radiology*, 2014; p. 140317.
10. Lee, C.I., et al., Comparative Effectiveness of Combined Digital Mammography and Tomosynthesis Screening for Women with Dense Breasts. *Radiology*, 2014; p. 141237.
11. McCarthy, A.M., et al., Screening outcomes following implementation of digital breast tomosynthesis in a general-population screening program. *J Natl Cancer Ins.* 2014; 106(11).
12. Rosenberg R.D., et al., Performance benchmarks for screening mammography. Radiology. Oct. 2006; 241 (1): 55-66. Erratum in: *Radiology*. 2014 May: 271(2):620.
13. Schell MJ et al. Evidence-based target recall rates for screening mammography. *Radiology*. June 2007; 243: 681-689.
14. Holland R, Mravunac M, Hendriks JH, Bekker BV. So-called interval cancers of the breast: pathologic and radiologic analysis of sixty-four cases. *Cancer* 1982;49(12):2527-2533.
15. McDonald E, et al., Effectiveness of Digital Breast Tomosynthesis Compared With Digital Mammography: Outcomes Analysis From 3 Years of Breast Cancer Screening. *JAMA Oncology Online*. February 18, 2016.
16. Bonafede M, et al., Value analysis of digital breast tomosynthesis for breast cancer screening in a commercially-insured US population. *ClincioEconomics and Outcomes Research.* 2015; 7: 53-63.
17. Lang K, Andersson I, Rosso A, Tingberg A, Timberg P, Zackrisson S. Performance of one-view breast tomosynthesis as a stand-alone breast cancer screening modality: results from the Malmo Breast Tomosynthesis Screening Trial, a population-based study. *Eur Radiol*. May 1 2015.
18. Bernardi D, Macaskill P, Pellegrini M, et al. Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM-2): a population-based prospective study. *The Lancet. Oncology*. Aug 2016;17(8):1105-1113.
19. Destounis S, Arieno A, Morgan R. Initial experience with combination digital breast tomosynthesis plus full field digital mammography or full field digital mammography alone in the screening environment. *Journal of Clinical Imaging Science.* 2014;4(1):1-6.
20. Rose SL, Tidwell AL, Ice MF, Nordmann AS, Sexton R, Song R. A Reader Study Comparing Prospective Tomosynthesis Interpretations with Retrospective Readings of the Corresponding FFDM Examinations. *Academic radiology*. 2014;21(9):1204-1210.

21. Sharpe RE, Jr., Venkataraman S, Phillips J, et al. Increased Cancer Detection Rate and Variations in the Recall Rate Resulting from Implementation of 3D Digital Breast Tomosynthesis into a Population-based Screening Program. *Radiology.* Oct 9 2015;142036.
22. Conant EF, Beaber EF, Sprague BL, et al. Breast cancer screening using tomosynthesis in combination with digital mammography compared to digital mammography alone: a cohort study within the PROSPR consortium. *Breast Cancer Res Treat.* Feb 2016;156(1):109-116.

Response of the Committee to Public Presentations: The Committee questioned public presenters on:

- the follow-up protocol after a positive DBT finding,
- the accuracy of DBT,
- the risk of over diagnosis, and
- the efficacy of DBT when used on dense breast tissue.

Clinical Evidence Presented to the Committee: See the following link to the evidence presented by CEbP at OHSU:
https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/breast_tomosynthesis_dossier_review_final.pdf

Summary of the Committee's deliberations: The Committee focused deliberations on:

- the availability of DBT for NYS Medicaid members, particularly those living in underserved and rural areas,
- whether there is sufficient outcome data to support a coverage recommendation,
- the harms associated with DBT, and
- the cost per DBT test.

Evidence-Based Systematic Assessment: See the "**Summary**" section on page 26 of CEbP at OHSU's evidence-based systematic assessment of DBT at the following link:
https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/breast_tomosynthesis_dossier_review_final.pdf

The Committee's Findings and Recommendations: The Committee reviewed the OHSU Report and the systemic assessment of the evidence reviewed and presented by the CEbP at OHSU. The Committee recommended coverage of DBT for the diagnosis and screening of breast cancer by a vote of 7 to 3.